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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,120	CHUA ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-27 are pending.

2. Applicant's amendment filed on 05/11/2006 is acknowledged.

3. Restriction is required under 35 U.S.C. 121 and 372.

4. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Blo t 5 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group II, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Blot t 1 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group III, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der p 1 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group IV, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der p 2 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group V, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der p 3 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group VI, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der fl allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group VII, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der f2 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group VIII, Claims 1-15, drawn to a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der f3 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, plasmids, vectors and vaccines and compositions thereof.

Group IX, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Blo t 5 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

Group X, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Blo t 1 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

Group XI, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der p 1 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

Group XII, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der p 2 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

Group XIII, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der p 3 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal

peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

Group XIV, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der fl allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

Group XV, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der f 2 allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

Group XVI, Claims 16-27, drawn to a method for immunization against an allergen comprising administering to a subject a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding a Der f3 allergen wherein the first signal

peptide mediates the translocation of the allergen into the endoplasmic reticulum, or further comprising an operably linked gene encoding a second signal peptide wherein the second signal peptide targets the allergen to an endosome or lysosome, and administering the allergen to the subject.

6. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I-VIII were found to have no special technical feature that defined the contribution over the prior art of Ruperti et al. (PTO-892, Reference U).

Ruperti et al. teaches a recombinant nucleic acid comprising a gene encoding a first signal peptide operably linked to a gene encoding an allergen wherein the first signal peptide mediates the translocation of the allergen into the endoplasmic reticulum (Sn20 allergen-like mRNA comprising a 19 amino acid putative signal peptide). (In particular, title, abstract, page 733, left column second paragraph).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

7. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C. 121: (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If any of Groups I-XVI is elected, applicant is further required to elect:

a single specific nucleic acid comprising:

a first signal peptide as recited in claims 3-4 and 9; and optionally

a second signal peptide as recited in claims 6-7 and 9.

If any of Groups IX-XVI is elected, applicant is further required to elect:

a single specific mode of administration as recited in claims 20-21, 23 and 26.

These species are distinct because the methods differ with respect to ingredients, method steps and endpoints; thus each method represents patentably distinct subject matter.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 26, 2007
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